IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application Of:	Examiner: James William Rogers
DesNoyer et al.	Art Unit: 1618
Serial No: 10/750,139	Confirmation No. 2159
Filed: June 3, 2004	
For: Poly(Ester Amide) Coating Composition For Implantable Devices	

Mail Stop: **Appeal Brief-Patents**
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

REPLY BRIEF

Dear Sir:

This Reply Brief is submitted pursuant to receipt of a Response to Appeal Brief mailed June 11, 2008

STATUS OF CLAIMS

Claims 1-58 are pending in the application. Claims 1-58 are rejected and form the subject of this appeal.

GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

The issues in this appeal as presented in the Appeal Brief are:

(1) Whether claim 4 is obvious over Roby in view of Pinchuk under 35 U.S.C. 103(a); and

(2) Whether claims 1-3, and 5-58 obvious over Pacetti 2 in view of Roby under 35 U.S.C. 103(a).

Note, the examiner presented the issues in the reverse order. The grounds of rejection are discussed in the order as originally presented.

ARGUMENT

In general, the Answer alleges (1) that an ordinary skill in the art would be motivated to combine the teachings of Roby and Pinchuk or Pacetti 2 and Roby (2) that a person of ordinary skill in the art would have a reasonable expectation of success of the combination of the teachings in the references. Appellants believe that the Appeal Brief deals with and overcomes fully the proffered grounds for rejection but wish to add the following a few points in response to the examiner's Answer:

(1). Claim 4 is non-obvious over Roby in view of Pinchuk under 35 U.S.C. 103(a)

To establish a prima facie obviousness of a claim over a combination of references, the examiner has to show that there is motivation for a person of ordinary skill in the art to combine the teachings of the references so as to arrive at the claimed subject matter (see MPEP §2143.01). The examiner fails to provide such motivation.

Roby discloses a PEA polymer that can be used to form a surgical device such as a surgical fiber. Roby further states that a PEA polymer combines the good mechanical properties of a polyamide with the degradability of a polyester (see page 3, lines 7 and 8). Pinchuk discloses an intravascular or intervascular medical device that

can be coated with a copolymer comprising an A block and a B block, the A-block including an alkyl chain and the B block including units from methacrylate monomers. Pinchuk also discloses that coating can further include blocks from polycaprolactone, polyglycolic acid, siloxane, etc. However, contrary to the examiner's assertion, Roby and Pinchuk fail to provide motivation for a person of ordinary skill in the art to combine the references. Other than showing a PEA or an AB block copolymer are known in the art, nothing in Roby and Pinchuk provides motivation for a person of ordinary skill in the art to combine the PEA polymer in Roby and the polymers in Pinchuk so as to make a coating as defined by claim 4.

In contrast, Applicants recognized there are problems associated with a coating formed of a PEA polymer on a stent. For example, these problems can be mechanical failures due to adhesion of the PEA polymer to a catheter balloon causing extensive balloon shear damage and damage to the luminal stent surface and lacking control of permeation/release of a hydrophilic drug (see page 2, lines 11-21 and Figure 1 of the instant application). A solution to address the latter issue used in the art is to use a thicker coating of PEA (see page 2, line 21 to page 3, line 2 of the instant application).

Applicants invented a different technology to address these problems and found that a low surface energy, surface blooming polymer that comprises a PEA miscible block or PEA miscible backbone can be used together with a PEA polymer to form a coating on an implantable device. A coating thus formed has enhanced mechanical and drug release rate properties. **Note, in this coating, the low surface energy, surface blooming attributes of the low surface energy, surface blooming polymer address the problems associated with adhesive properties of a PEA polymer in the coating while the PEA miscible block or PEA miscible backbone attributes of the low surface energy, surface blooming polymer addresses the issue of lacking drug release control by by coating of a PEA polymer**. The motivation for this unique approach is completely missing in either Roby or Pinchuk or both.

Contrary to the examiner's assertion, a person of ordinary skill in the art would NOT have a reasonable expectation of success of the combination Roby and Pinchuk (see *KSR International Co. v. Teleflex Inc.*, 550 U.S. ___, ___, 82 USPQ2d 1385, 1395 (2007); *Sakraida v. AG Pro, Inc.*, 425 U.S. 273, 282, 189 USPQ 449, 453 (1976); *Anderson's-Black Rock, Inc. v. Pavement Salvage Co.*, 396 U.S. 57, 62-63, 163 USPQ

673, 675 (1969); *Great Atlantic & P. Tea Co. v. Supermarket Equipment Corp.*, 340 U.S. 147, 152, 87 USPQ 303, 306 (1950)). To have an expectation whatsoever of success of a solution to a problem, one has to first identify the problem, and both Roby and Pinchuk fail to do so (see the preceding discussions).

In the Examiner's Answer, the examiner asserts there is motivation for a person of ordinary skill in the art to combine the teachings of Roby and Pinchuk since "all the claimed elements such as PEA and the copolymers of claim 4 were known to be useful in coating medical devices and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions and the combination would have yielded predictable results..." (the Examiner's Answer, page 6, paragraph 4). This alleged motivation that a PEA polymer OR a polymer of claim 4 is useful in coating medical devices does not remotely relate to the problems of a coating formed of a PEA polymer and thus is not motivation for a person of ordinary skill in the art to combine Roby and Pinchuk (see the discussions above). Suffice it to say, a combination of known elements can be novel and non-obvious over known elements.

With respect to the examiner's assertion that a person of ordinary skill in the art would have a reasonable expectation of success of the combination of Roby and Pinchuk since the combination would have yielded predictable results, Applicants submit this assertion is unfounded and believe the above discussion fully addresses this assertion. As evidence, to address the issue of lacking control of release of a hydrophilic drug from a coating of a PEA polymer, a thicker coating of a PEA polymer is used to enhance control of drug release property of the coating (page 2, line 21 to page 3, line 2 of the instant application) (see the discussion above). However, a thicker coating of a PEA polymer would probably result in more mechanical failures because of the adhesiveness of the PEA polymer. This shows that a proposed solution to address one issue in a coating of a PEA polymer may leave another issue of the coating untapped or cause another issue to worsen. Therefore, the method as defined by claim 4 is not predictable over Roby and Pinchuk (see the discussions above).

In sum, the examiner fails to establish that claim 4 is *prima facie* obvious over Roby in view of Pinchuk under 35 U.S.C. §103(a).

(2). Claims 1-3, and 5-58 are non-obvious over Pacetti 2 in view of Roby under 35 U.S.C. 103(a)

The examiner fails to show that there is motivation for a person of ordinary skill in the art to combine the teachings of Pacetti 2 and Roby so as to arrive at the claimed subject matter (see MPEP §2143.01).

Pacetti 2 discloses a coating for reducing the release rate of drugs from stents. the stent includes a polymer capable of maintaining its crystalline lattice structure while the therapeutic agent is released from the coating. Such polymers can be polyurethanes with polydimethylsiloxane soft segments, poly(vinylidene fluoride-co-methacrylic acid), styrene-ethylene-styrene block copolymer, and polytetrafluoroethylene, etc (see paragraphs [0020] and [0021]).

Roby is discussed above.

Contrary to the examiner's assertion, Pacetti 2 and Roby fail to provide motivation for a person of ordinary skill in the art to combine the references. Other than showing a PEA or an AB block copolymer are known in the art, nothing in Pacetti 2 and Roby provides motivation for a person of ordinary skill in the art to combine the polymers in Pacetti 2 and the PEA polymer in Roby so as to make a coating as defined by claims of the instant application. None of Pacetti 2 and Roby recognize the issues of mechanical failure and lacking control of release of a drug in a coating formed of a PEA polymer (see the discussion of non-obviousness of claim 4, *supra*). The examiner fails to show there is motivation for a person of ordinary skill in the art to combine Pacetti 2 and Roby (see the discussion of non-obviousness of claim 4, *supra*). The examiner further fails to show that a person of ordinary skill in the art would have a reasonable expectation of success of combining Pacetti 2 and Roby (see the discussion of non-obviousness of claim 4, *supra*).

The examiner asserts the motivation to combine Pacetti 2 and Roby would be (1) bioabsorbability and good mechanical properties of a PEA polymer disclosed in Roby, and (2) control of release of drug by the crystalline polymers disclosed in Pacetti 2 (page 5, 2nd paragraph, of the Examiner's Answer). Again, these alleged advantages are not germane to the issues associated the coating of a PEA polymer as Applicants recognized (see page 2, lines 11 to page 3, line 2; Figure 1; see also the discussion of non-obviousness of claim 4, *supra*). If the bioabsorbability of a PEA polymer truly

provided motivation for a person of ordinary skill in the art to use a PEA polymer in connection with another polymer, then a person of ordinary skill in the art would be taught away from combining Roby with Pacetti 2 since polymers such as styrene-ethylene-styrene block copolymer and poly(vinylidene fluoride-co-methacrylic acid) disclosed in Pacetti 2 are non-absorbable or biodurable polymers.

In sum, the examiner fails to establish that claims 1-3, and 5-58 are *prima facie* obvious over Pacetti 2 in view of Roby under 35 U.S.C. §103(a).

CONCLUSION

The examiner has failed, as a matter of law, to set forth a case of obviousness of claim 4 under 35 U.S.C. 103(a) over Roby in view of Pinchuk.

The examiner has failed, as a matter of law, to set forth a case of obviousness of claims 1-3, 5-58 under 35 U.S.C. 103(a) over Pacetti 2 in view of Roby.

Appellants therefore respectfully request that the Board reverse the rejections and order the application to be passed to issue.

Date: August 1, 2008

Respectfully submitted,

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